## EXHIBIT J

## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20857

NDA 22-081

Gilead Colorado, Inc. Attention: Ms. Linnea Tanner Director, Regulatory Affairs 7575 West 103<sup>rd</sup> Ave., #102 Westmister, CO 80021-5426

Dear Ms. Tanner:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Letairis (ambrisentan) 5 and 10 mg Tablets

Date of Application: December 13, 2006

Date of Receipt: December 18, 2006

Our Reference Number: NDA 22-081

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on February 16, 2007 in accordance with 21 CFR 314.101(a).

Please cite the NDA number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration Center for Drug Evaluation and Research Division of Cardiovascular and Renal Products 5901-B Ammendale Road Beltsville, MD 20705-1266

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Per \_\_\_\_\_\_\_

If you have any questions, please contact:

Ms. Melissa Robb Regulatory Health Project Manager (301) 796-1138

Sincerely,

{See.appended electronic signature page}

Edward Fromm
Chief, Project Management Staff
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Edward Fromm 1/10/2007 02:31:37 PM